

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

### **I. CLAIM STATUS**

Claims 1-7 and 9-37 were pending when last examined.

The Examiner has withdrawn claims 15-36 from consideration as nonelected subject matter. Applicants respectfully request that the Examiner reinstate claims 16, 17, 19 and 24 for the reasons discussed below.

Claims 2-7 have been cancelled.

Applicants reserve the right to file a Continuation or Divisional application on the cancelled subject matter.

Claims 1-7, 9-14 and 37 were examined and are rejected.

Claim 1 has been amended to recite the nucleotide sequence of the wild-type human AGT. Support for such claim can be found in SEQ ID NO: 1.

Further, claim 1 has been amended to recite wherein between 6 and 25 amino acids of the wild type human AGT are substituted by other amino acids. Support for such amendment can be found in the specification as file, for example, page 13, lines 34-35.

New claim 38 is directed to the functional properties of the AGT mutant of claim 1. Support for such amendment can be found in the specification as filed, for example, page 3, lines 1-15; page 5, line 14 to page 9, line 10.

New claims 39-44 are directed to further advantageous properties of the AGT mutant of claim 1. Support for such amendment can be found in the specification as file, for example page 9, line 15 to page 13, line 26, and cancelled claims 2-7.

All amendments are made without acquiescence to the correctness of the Office, and merely to expedite examination.

No new matter has been added.

## II. ELECTION/RESTRICTION

On page 3 of the Office Action, the Examiner contends that claims 16, 17, 19, 20 and 24 do not read on the elected species because the mutant of claims 16-17 and 19-20 does not have a Gly at position 150 and the mutant of claim 24 has a deletion of Leu34.

Applicants respectfully assert that claims 16, 17, 19 and 24 do read on the elected species.

(a) Claim 16 reads,

The AGT mutant according to claim 1 with modifications Cys62Ala, Gln115Ser, Gln116His, Lys125Ala, Ala127Thr, Arg128Ala, Gly131Lys, Gly132Thr, Met134Leu, Arg135Ser, Cys150Asn, Ser151Ile, Ser152Asn, Asn157Gly, Ser159Glu, truncated after Gly182 and optionally 1 to 10 additional amino acid modifications.

Claim 17 reads,

The AGT mutant according to claim 16 with modifications Cys62Ala, Gln115Ser, Gln116His, Lys125Ala, Ala127Thr, Arg128Ala, Gly131Lys, Gly132Thr, Met134Leu, Arg135Ser, Cys150Asn, Ser151Ile, Ser152Asn, Asn157Gly, Ser159Glu, truncated after Gly182 and optionally 3 to 7 additional amino acid modifications.

Therefore, claims 16 and 17 encompass the following 6 additional amino acid modifications: Lys32Ile, Leu33Phe, Asn150Gly, Ile151Gly, Asn152Asp and Ala154Asp.

Accordingly, claims 16 and 17 fall within the elected species.

(b) Claim 19 reads,

The AGT mutant according to claim 1 with modifications Cys62Ala, Gln115Ser, Gln116His, Lys125Ala, Ala127Thr, Arg128Ala, Cys150Asn, Ser151Ile, Ser152Asn, Asn157Gly, Ser159Glu, truncated after Gly182 and optionally 1 to 10 additional amino acid modifications.

Therefore claim 19 encompasses the following 10 additional amino acid modifications: Lys32Ile, Leu33Phe, Gly131Lys, Gly132Thr, Met134Leu, Arg135Ser, Asn150Gly, Ile151Gly, Asn152Asp, Ala154Asp.

Accordingly, claim 19 falls within the elected species.

(c) Applicants agree with the Examiner that claim 20 does not read on the elected species.

(d) Claim 24 reads,

The AGT mutant according to claim 1 with modifications Lys32Ile, Leu33Phe, Cys62Ala, Lys125Ala, Ala127Thr, Arg128Ala, Cys150Gly, Ser151Gly, Ser152Asp, Ala154Asp, Asn157Gly, Asn157Gly, Ser159Glu, truncated after Gly182 and optionally further mutations selected from

Gln115Ser, Gln116His; and

Gly131Lys, Gly132Thr, Met134Leu, Arg135Ser. It is noted that “deletion of Leu 34” is optional.

Thus, claim 24 encompasses the modifications listed in the first half of the claim, and optionally, mutations selected from, Gln115Ser, Gln115His, and Gly131Lys, Gly132Thr, Met134Leu, Arg135Ser. Therefore, a species of amended claim 24 reads on the elected species.

(e) Therefore, Applicants assert that claims 1-7, 9-14, **16, 17, 19, 24** and 37 read on the elected species and should be examined. In light of the arguments discussed above, the Examiner is respectfully requested to rejoin these claims.

### **III. REJECTION UNDER 35 USC § 101**

On pages 4 and 5 of the Office Action, claims 1-7 and 9-14 are rejected under 35 USC § 101 as being directed to a non-statutory subject matter.

Specifically, the Examiner contends that the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products, such as being “isolated.”

Claim 1 has been amended to recite the term “isolated.” Moreover, new claims 38-44 are also directed to the “isolated” AGT mutant. Accordingly, this rejection is overcome and should be withdrawn.

#### **IV. REJECTION UNDER 35 USC § 112**

On pages 5 of the Office Action, claims 1-7 and 9-14 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner contends that it is unclear what amino acid residue in a given human AGT, is the amino acid “Cys62” or the “1-4 amino acids at the N-terminus or 1-40 amino acids at the C-terminus.” Therefore, the Examiner asserts that this rejection can be overcome by providing a sequence identifier for the wild type human AGT.

Applicants respectfully traverse this rejection. Further, this rejection is inapplicable to new claims 38-44.

Specifically, claim 1 has been amended to recite the nucleotide sequence for the wild type human AGT. Support for such amendment can be found in SEQ ID NO: 1 and the specification as filed, for example, page 1, line 19. Moreover, new claims 38-44 depend on claim 1 and therefore recite the nucleotide sequence for the wild type human AGT.

Accordingly, this rejection is overcome and should be withdrawn.

#### **V. REJECTION UNDER 35 USC § 102**

On pages 6 and 7 of the Office Action, claims 1-5, 9-13 and 37 are rejected under 35 USC § 102(b) as being anticipated by Juillerat et al. (Chemistry & Biology, 2003). Applicants note that on page 7, the Examiner alleges that the reference of Kusakabe et al. anticipates claims 1-5, 9-13 and 37. See last sentence of the first paragraph on page 7 of the Office Action. However, the Examiner has presented no arguments in this respect, nor has the Examiner provided a copy of the reference. Therefore, all arguments presented below are directed to the Juillerat et al. reference.

Applicants respectfully traverse this rejection. Further, this rejection is inapplicable to new claims 38-44.

Specifically, amended claim 1 is directed to an AGT mutant wherein between 6 and 25 amino acids of the wild type human AGT are substituted by other amino acids. In contrast, only 1-4 amino acids are substituted in the AGT mutant of Juillerat et al. Since the Juillerat et al. mutant is limited to only 1-4 amino acid substitutions, it cannot anticipate the at least 6 amino acid substitutions of the claimed invention.

Moreover, new claims 38-44 depend on claim 1. Since Juillerat et al. is ineffective to anticipate amended claim 1, such rejection is inapplicable to the new claims.

Accordingly, this rejection is overcome and should be withdrawn.

## VI. EXAMINER COMMENTS

Applicants assert that all grounds for rejections, specifically, the rejection under 102(b), have been overcome by the amendment of claim 1. Accordingly, the Examiner is respectfully requested to re-examine the Markush-type claims as indicated on page 7 of the Office Action.

## CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

***The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975, with the EXCEPTION of deficiencies in fees for multiple dependent claims in new applications.***

Respectfully submitted,

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